

## REMARKS

Entry of the above amendments and consideration of the following remarks are respectfully requested. Upon entry of the above amendments, this application will contain claims 1-21 pending and under consideration. Claims 1-15 stand rejected under 35 U.S.C. §112, second paragraph. Claims 1-21 stand rejected under 35 U.S.C. §103(a) over de Boer et al. (U.S. 5,518,751) in view of Satter et al. (U.S. 5,770,247). For the reasons discussed below Applicants believe that the claimed invention is patentable over the cited art and request reconsideration leading to timely allowance of this application.

### Rejections under 35 U.S.C. 112

Claims 1-15 stand rejected under 35 U.S.C. §112, second paragraph for failing to enable one skilled in the art to use the invention commensurate with the scope of the claims. Applicants respectfully disagree with the Examiner's conclusion, noting in particular that the Examiner considered only page 9 of the application on which to base this rejection.

An enablement rejection involves a two step inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. Not everything necessary to practice the invention needs to be disclosed. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. (MPEP §2164.08 and references cited therein.)

Applicants respectfully maintain the specification clearly enables one skilled in the art to be able to make and use the claimed invention. On the outset it should be noted that the skill level for the relevant art is clearly very high.

Secondly, the enablement bears a reasonable correlation to the scope of the claims. One does not look to the claims but the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc. v. Garlock, Inc.* 220, USPQ 303, 316-17 (Fed. Cir. 1983). The application clearly provides that CLA refers to positional isomers and

geometric isomers of linoleic acid. Linoleic acid is a  $C_{18}H_{32}O_2$  carboxylic acid with two double bonds. (Merk Index, Twelfth Ed. 1996, page 940, reference number 5529.) Positional isomers and geometric isomers are clearly discussed. (Application, page 9, lines 13-29.) Examples CLA esters are listed and include monoglycerides, diglycerides and triglycerides (Id. page 9, lines 9-10.)

Even in the relative unpredictable chemical arts, one need not necessarily disclose how to make each and every embodiment encompassed by the claim. *In re Angstadt*, 190, U.S.P.Q. 214, 218-219 (C.C.P.A. 1976) (See also *In re Wands*, 8, U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation, the key word is 'undue' not 'experimentation'"). Since linoleic acid is a carboxylic acid, one skilled in the art would be able to prepare an ester or salt without undue experimentation. Further the application discusses commercial sources and relevant references teaching methods of isolation and synthesis of the acid, salt and esters. (Application pages 9 line 30 -12 line 15.) The application clearly provides considerable direction and guidance on how to practice the invention and presents working examples. (Application Examples 2-4, pages 19 line 17- page 29 line 4.) This provides explicit experimental details for determining the activity or potency of the claimed compositions by determining blood glucose and insulin levels. From these experiments, one can determine relative therapeutic amounts for different species. Procedures for screening potential compositions for treating diabetes and determining their relative activity were known prior to 1997, and examples of these procedures are specifically described in the application in these examples. Further the claimed compositions were evaluated along side Rezulin--a composition known to treat diabetes. (Application page 24, line 5- page 29, line 4 and Figs. 6, 8, and 10.)

Applicants respectfully maintain the invention is adequately enabled for one skilled in the art to make the claimed compounds and to use these compounds to treat diabetes in animals. Applicants believe these rejections are overcome and request their withdrawal.

### Rejections under 35 U.S.C. 103

Claims 1-21 stand rejected under 35 U.S.C. §103(a) over de Boer et al. in view of Satter et al. Applicants respectfully disagree with the Examiner's characterization of these two references. These references considered either singly or in combination do not make the claimed invention obvious. The entire reference must be considered for what it teaches and suggests. It is impermissible within the framework of a §103 rejection to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary for the full appreciation of what the reference fairly suggests to one skilled in the art. *In re Wesslau*, 147 U.S.P.Q. 391, 393 (CCPA 1965).

The de Boer et al. reference actually states:

"An important reason for enriching milk or milk powders with fats containing a high percentage of unsaturated fatty acids or strongly unsaturated fatty acids is to prevent or reduce cardiovascular diseases, atopies, rheumatic disorders or diabetes. In particular, such products contain a high percentage of oleic acid, linoleic acid which may or may not be conjugated,  $\alpha$ -linolenic acid and unsaturated C<sub>20</sub> and C<sub>22</sub> fatty acids." (de Boer et al. col. 1, lines 35-42.)

There is no other mention of diabetes or any other disorder in this reference. Further and more importantly this passage does not specify which unsaturated fatty acid or strongly unsaturated fatty acid is active against which disorder. At best this reference is merely an invitation to experiment. The sheer number of disorders encompassed in the listing is enormous. Most of the disorders are in reality broad classes of disorders or diseases. For example, the number of cardiovascular disorders by itself is enormous. Each disorder is a result of a specific physiological deficiency or problem. Each specific physiological deficiency or problem requires a specific treatment. In fact, this reference does not fairly suggest that linoleic acid has any activity against any of the listed disorders. It merely states enriching milk with fats that contain compounds called unsaturated fatty acids or strongly unsaturated fatty acids may prevent or treat the listed disorders.

This reference provides absolute no guidance to one skilled in the art, which compound(s) among those mentioned could possibly have any activity against a disorder. The sheer number of compounds included within the classes of compounds mentioned is enormous. Unsaturated fatty acids encompass literally thousands of compounds. The

term strongly unsaturated fatty acid is not even defined. One cannot determine from this description whether it is the milk, the fats, the unsaturated fatty acids or the strongly unsaturated fatty acids--what ever they are-- that can be used to treat the listed disorders. Query: does this reference suggest or teach use of conjugated or unconjugated isomers? Simply put this reference does not teach or suggest to one skilled in the art which compound(s) should be investigated.

When considered as a whole this reference does not guide any one skilled in the art to Applicants' claimed invention.

Satter et al. does not make up for the deficiencies of de Boer et al. Satter et al. merely provides that feeding lactating cows a diet, which contains vegetable oil rich in linoleic or linolenic acid, enriches the linoleic acid as a percentage of the total fatty acid in the cows' milk. This raises the question, why feed the vegetable oil rich in linoleic acid to the cows--why not use this oil directly for treatment? But then this reference does not mention any disorder or treatment of a disorder. This reference only teaches that CLA is known to possess beneficial effects for humans. This is hardly a motivation to use CLA in the treatment of diabetes.

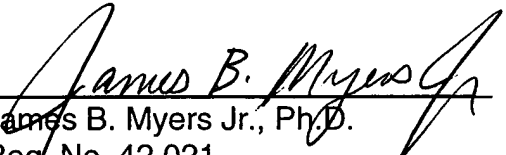
Applicants suggest that these references considered either singly or combined do not make the claimed invention obvious. The de Boer et al. reference does little more than to invite one to experiment; no specifics as to which a disorder to investigate or which compound to consider are provided. Satter et al. does not make up for these deficiencies. This reference only notes that CLA provides beneficial effects. This amounts to little more than hindsight reconstruction of Applicants' claimed invention--for without considering the specific disclosure in the present application there is no reasonable suggestion or teaching that compositions containing CLA can be used to treat diabetes.

## Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the cited references, either singly, or in combination, do not disclose or make obvious the claimed invention. Accordingly, reconsideration leading to withdrawal of all the rejections under 35 U.S.C. §§112 and 103(a) and passage of this application containing claims 1-21 are

respectfully requested. Additionally, the Examiner is invited to telephone the undersigned attorney if there are any questions about this submission or other matters, which may be addressed in that fashion.

Respectfully submitted,

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**VERSION WITH MARKINGS TO  
SHOW CHANGES**

9. (Amended) The method of claim 1, wherein said GLA conjugated linoleic acid is comprised predominantly of cis,trans-9,11-octadecadienoic acid and trans,cis-9,11-octadecadienoic acid.

10. (Amended) The method of claim 1, wherein said GLA conjugated linoleic acid is comprised predominantly of cis,cis-9,11-octadecadienoic acid.